

Treatment of Acute Proximal Anterior Cruciate Ligament Tears – Part 1

Gap Formation and Stabilization Potential of Repair Techniques

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Background: Recently, there has been a resurgence of interest in primary repair of the anterior cruciate ligament (ACL), with fixation techniques evolving. However, to date, there have been no biomechanical studies comparing fixed to adjustable fixation repair techniques.

Hypothesis: Adjustable ACL repair provides for improved stabilization compared with fixed techniques with respect to both gap formation and residual load-bearing capability.

Study Design: Controlled laboratory study.

Methods: A total of 4 different ACL repair techniques ($n = 5$ per group), including single- and double-cinch loop (CL) cortical button fixation as well as knotless single-suture anchor fixation, were tested using a porcine model. For adjustable single-CL loop fixation, additional preconditioning (10 cycles at 0.5 Hz) was performed. The force after fixation and the actuator displacement to achieve a time-zero preload of 10 N were measured for fixed techniques. Incrementally increasing cycling (1 mm/500 cycles) from 1 to 8 mm was performed for 4000 cycles at 0.75 Hz before pull to failure (50 mm/min). The final residual peak load and gap formation for each test block were analyzed as well as ultimate strength.

Results: Knot tying of a single-CL over a button (mean \pm SD, 0.66 ± 0.23 mm) and knotless anchor fixation (0.20 ± 0.12 mm) resulted in significant time-zero gaps ($P < .001$) and significantly higher overall gap formation at reduced residual loading (analysis of covariance, $P < .001$) compared with both the double-CL loop and adjustable fixation techniques. The adjustable group showed the highest failure load and stiffness, at 305.7 N and 117.1 N/mm, respectively. The failure load of the knotted single-CL group was significantly reduced compared with all other groups ($P < .001$).

Conclusion: Adjustable single-CL cortical button fixation with intraoperative preconditioning optimized time-zero ACL tension and led to significantly improved stabilization and reduced gap formation, with the highest ultimate strength. Single-CL loop knot tying over the button and knotless anchor fixation resulted in time-zero gaps to achieve slight tension on the ACL and significantly higher gap formation at reduced load-bearing capability.

Clinical Relevance: Although the clinical relevance of gap formation is uncertain, a biomechanical understanding of the stabilization potential of current ACL repair techniques is pertinent to the continued evolution of surgical approaches to enable better clinical outcomes.

Keywords: ACL repair; adjustable loop; suspensory fixation; gap formation; biomechanical testing

Open anterior cruciate ligament (ACL) repair was reported as the first surgical treatment for ACL injuries over 100 years ago, and despite promising initial short-term

outcomes,^{25,36,48} longer follow-up data were disappointing, with high rates of instability, pain, and stiffness.^{12,21,37} This resulted in ACL reconstruction becoming the state-of-the-art treatment for ACL injuries.^{41,45} Although the results of ACL reconstruction are generally good, with low failure rates and acceptable return-to-sport rates in the athletic population, significant challenges remain because

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of both donor site morbidity^{14,39} and the loss of proprioception that influences neuromuscular function negatively.^{6,31}

Modern-day arthroscopic ACL repair aims to circumvent these issues by preserving the native ACL. The new approaches show that the unpredictable clinical outcomes of the past can be significantly improved by more appropriate patient selection that includes only treating patients with proximal tears and good tissue quality^{5,16,46,47} so as to allow for better blood supply.⁴³

In the studies reporting improved outcomes after primary repair of proximal ACL tears, multiple approaches have been used for suturing and femoral fixation techniques with a suture anchor or button.^{1,7,8,10,17-20,28,38} ACL suturing methods have mainly consisted of either cinch loop (CL) techniques or modified Bunnell-type stitch configurations. A previous biomechanical evaluation reported that primary proximal ACL repair with either suture knot tying over a cortical button or knotless suture anchor fixation demonstrated an overall gap formation of less than 1 mm after knee cycling with simulated active quadriceps force.⁴⁴ In contrast, other biomechanical studies^{13,23} showed increased laxity of up to 12 mm after primary ACL suture stabilization and applying cyclic loading in the anteroposterior (AP) direction. Similar to graft fixation for ACL reconstruction,^{26,29} the utilization of an adjustable loop device (ALD) for ACL repair may provide for additional intraoperative preconditioning compared with fixed techniques and could lead to improved stabilization with reduced gap formation. To date, however, there have been no studies that evaluate the use of an ALD for primary ACL repair. Because of the paucity of biomechanical data on the stabilization potential of ACL repair in terms of resulting gap formation and load-bearing capability, there are still concerns about the capacity of nonaugmented ACL repair techniques to restore normal knee function.

Therefore, the purpose of this study was to evaluate and compare the overall gap formation and residual peak load behavior as well as the ultimate strength of an adjustable technique to 3 different fixed ACL repair techniques with knotless suture anchor and knotted cortical button fixation in a biomechanical in vitro study using a porcine model. It was hypothesized that an adjustable ACL repair technique would provide for improved results compared with fixed repair techniques with respect to both gap formation and residual load-bearing capability.

METHODS

Test Groups

A knotless single-suture anchor ACL repair technique with multiple cross-type stitching to the ACL (group 1) and 3 different repair techniques with CL fixation and suture knot tying over the cortical button were studied (Figure 1). Button groups consisted of single-CL adjustable fixation (group 2; CLS-ALD) and 2 fixed techniques with single-CL fixation (group 3; CLS) and double-CL fixation (group 4; CLD) of the ACL. Suture knot tying over the button or knotless suture anchor fixation are representative methods for fixed ACL suspension without having additional intraoperative preconditioning options after primary fixation. For each testing group, 5 samples were used, resulting in a total of 20 samples. For the assessment of time-zero gap formation, overall 25 samples for each technique were used.

Specimen Preparation

A total of 20 freshly harvested porcine tibias and femurs (aged 8 months), collected from a local slaughterhouse, were utilized to create different ACL repair constructs. Porcine tibias with preserved ACLs and femurs were chosen because of previously reported morphometric and mechanical similarity to young adult human bones and tendons.^{2,22,30} The porcine tibias and femurs were initially prepared by removing all the soft tissue from the bone. The tibias were potted in a 2-component polyurethane fast cast resin (RenCast; Huntsman Advanced Materials) in line with the ACL long axis (Figure 1B). The ACL was released from the femoral footprint, measured with a digital caliper from the center of the tibial footprint along the longitudinal axis, and cut to a constant length of 30 mm. An ACL guide was used to pass a 2.4-mm pin through the lateral wall of the notch within the center of the native ACL footprint and out the proximal lateral cortex at a distance of 15 mm proximal and 5 mm anterior to the lateral epicondyle.¹⁵ A bone block of 32 mm in diameter and 35 mm in length was extracted along the guide pin by using a cylinder drill and sawing off the medial bone portion. The cylindrical bone block was docked in a custom-made steel fixture (Figure 1B).

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Ethical approval was not sought for the present study.

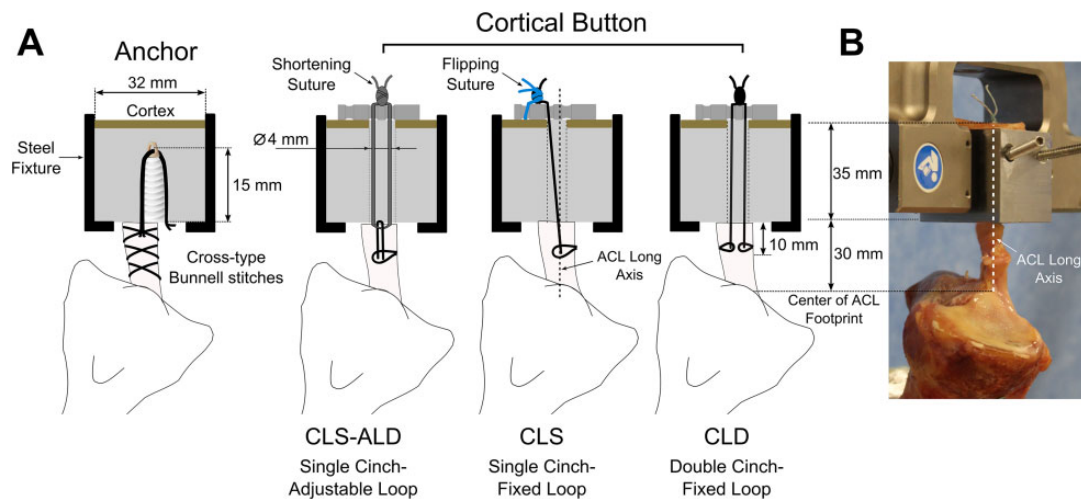


Figure 1. (A) Schematic illustration of the bone tunnel and anterior cruciate ligament repair-related definitions for anchor and cortical button repair techniques with the (B) final experimental setup.

The femoral-sided bone block was equipped with a continuous tunnel 4 mm in diameter for cortical button specimens and an anchor-specific drill hole 3.7 mm in diameter. Prepared specimens were stored at -20°C and thawed overnight before testing.

The embedded tibia and femoral-sided custom-made steel fixture with the inserted bone block were secured to the base plate and actuator of a dynamic testing machine (ElectroPuls E10000; Instron) using custom clamps and a 2-kN load cell mounted to the actuator (Figure 1B). Before testing, the overall initial distance from the femoral cortex to the ACL footprint was set to 65 mm to allow full reattachment of the ACL stump to the femoral block (Figure 1). All tests were performed at room temperature, and soft tissue was kept moist with physiological saline solution during preparation and testing.

ACL Repair Techniques

Essentially, 3 different repair techniques based on simple CL with cortical button fixation, as well as knotless suture anchor fixation, were applied to reattach the ACL to the femur. For all repair techniques, a suture passer was used for affixing the repair suture to the cut femoral ACL.

For cortical button groups, either 1 (CLS-ALD/CLS) or 2 (CLD) FiberSnare sutures (Arthrex) were utilized, which consists of a single No. 2 suture with a small loop at one end. CL fixation for the fixed groups (CLS, CLD) was performed by passing the suture at a distance of 10 mm from the cut end of the ligament through the ACL for closing the cinch by transferring the suture through the looped end. By pulling the suture end, the cinch was tightened around the enclosed portion of the ligament.

For the adjustable group (CLS-ALD), the loop portion of the repair suture was linked to an ALD (Figure 2A). After passing the loop portion of the repair suture through the ACL, the ALD was transferred through the shuttled loop of

the repair suture to tighten for CL closure (Figure 2B). Finally, the suture was cut close to the repair suture loop (Figure 2C). For single- (CLS, CLS-ALD) and double-CL fixation (CLD), only the anteromedial bundle and both major bundles were reattached, respectively (Figure 1A).

For knotless suture anchor fixation, 3 cross-type Bunnell stitches, starting from the intact distal ACL stump, were used for each No. 2 suture limb connecting both ACL bundles (Figure 2D). Final suture locking passes through the ACL below the most proximal Bunnell stitches exited the cut end of the ligament to ensure that the tissue sat down flush to the repair construct.

Femoral Fixation

ACL repair sutures for button fixation were threaded through the central holes of the button (TightRope RT Button; Arthrex) before passing the button through the femoral tunnel until flipping on top of the femoral cortex. Then, the button insertion and flipping sutures were removed for the CLD and CLS-ALD groups. For the CLS constructs, a flipping suture remained in position for later knot tying (Figure 1A). For knotless suture anchor fixation, the 2 suture limbs were shuttled through the anchor eyelet (4.75-mm BioComposite SwiveLock; Arthrex).

Once the repair sutures were in place, a manual 50-N pull over 5 seconds was performed using a spring-loaded tensiometer to simulate intraoperative single-hand tensioning and to remove settling effects as well as enable homogeneous engagement of the repair sutures before final fixation.³ All fixed groups were secured at this point by suture knot tying over the button with 4 half-hitch knots using an arthroscopic knot pusher or knotless suture anchor fixation within the femoral bone (Figure 3, point b). For knot tying of the single repair suture of the CLS group, an externally positioned No. 2 flipping suture next to the shuttled repair suture was used.

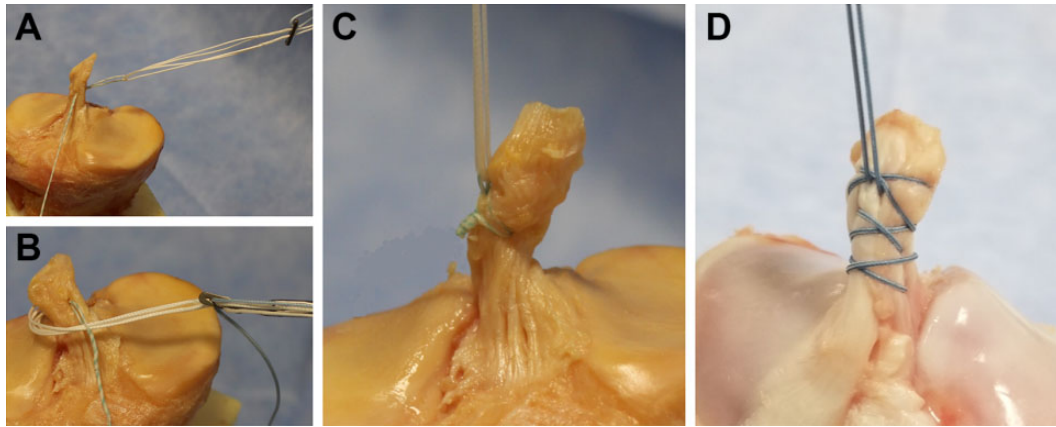


Figure 2. (A) Repair suture and (B) adjustable loop cortical button device shuttle through the anterior cruciate ligament (ACL) and repair suture loop for closing the cinch. (C) ACL repair with single-cinch loop adjustable cortical button and (D) cross-type Bunnell suture technique for knotless anchor fixation.

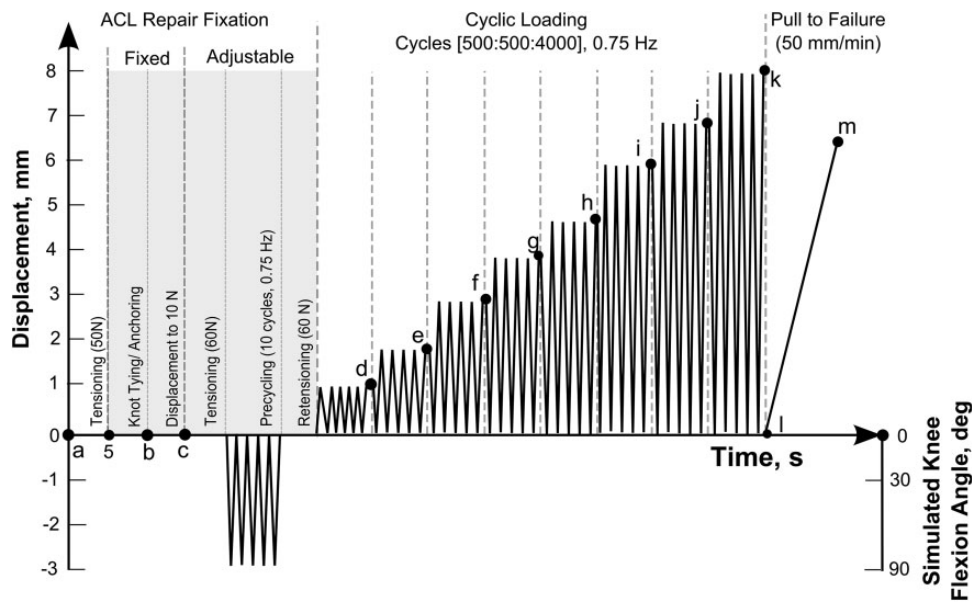


Figure 3. Schematic testing protocol with points of data analysis (*a-m*). Metrics for comparisons included initial load level after cortical button and suture anchor fixation (*b*), time-zero gap formation (Δbc), residual peak load and gap formation ($\Delta cd-\Delta ck$), and ultimate load and stiffness during pull to failure (Δ/m).

During femoral knotting or anchoring, the test machine's actuator was locked in position. Because the applied load after knot tying and anchoring varied, the test machine actuator was moved to reach a defined time-zero preload of 10 N to guarantee similar and reproducible initial testing conditions (Figure 3, point *c*). Based on the achieved tension levels after suture knot tying or anchoring during pretests, the time-zero ACL preload should represent an upper tension limit, which can be reached with these fixation methods.

Because no restriction of the primary tension was considered for the adjustable group, specimens were manually tensioned to a higher time-zero ACL preload (60 N) by

alternating tensioning of the loop shortening strands and were kept knotless thereafter for later preconditioning. Therefore, no initial gap was recorded. The CLS-ALD time-zero preload was chosen as the representative load-carrying capacity to protect the ACL during the first few weeks after repair.³² The time-zero position served as a reference for later dynamic elongation analysis and simulated a knee in full extension.

Biomechanical Testing

After ACL repair fixation and achieving the time-zero preload, the actuator position of the test machine was balanced

to zero to allow for comparing cyclic ACL repair test results. The tensile load was applied in line with the long axes of the repaired ACL and femoral tunnel to simulate a “worst-case” loading condition (Figure 1B).

It has been shown that the native ACL experiences approximately 3 mm of length change between full extension and 90° of weightbearing knee flexion.²⁴ In this regard, a position-controlled loading profile was used in this study, which allowed for simulating intraoperative knee flexion activity for ACL repair preconditioning (Figure 3). After primary fixation, CLS-ALD specimens underwent precycling by actuator translation between the time-zero position and -3 mm of slackening for a total of 10 cycles at 0.5 Hz, simulating intraoperative knee flexion activity between full extension and 90° of flexion. Thereafter, retensioning to 60 N was manually performed in a simulated full-extension knee position before ALD knotting.

Cyclic loading was performed in a position-controlled mode between 0 and 1 mm at a frequency of 0.75 Hz for 500 cycles. The peak elongation was then increased in 1-mm increments every 500 cycles up to 8 mm, for a total of 4000 cycles. ACL repair soft tissue fixation is a rather force-sensitive procedure with accelerated damage and elongation at small load changes. Thus, position-controlled cycling was utilized by simulating displacement in the range of normal and abnormal AP laxity. Finally, test samples were displaced during a pull-to-failure test at 50 mm/min. Load-displacement data during cycling and pull to failure were recorded using WaveMatrix software (Instron) with a sampling rate of 500 Hz.

Outcome Data

Metrics for comparisons included data of ACL repair fixation, cycling, and pull to failure. For fixed ACL repair techniques (CLS, CLD, anchor), the initial load level after cortical button and suture anchor fixation (Figure 3, point *b*) and subsequent displacement (Δbc) to reach the final time-zero preload position (10 N) were recorded. The aforementioned initial displacement represents the “time-zero gap formation.”

For cyclic loading, the final hysteresis curve of each elongation block (each 500th cycle) was analyzed to determine the residual peak load and gap formation. The residual peak load at the end of each test block (Figure 3, points *d* through *k*) refers to the final load-bearing capability of each ACL repair construct. “Gap formation” represents plastic deformation (laxity) with no load (<1 N) on the construct in the force-displacement progression. The overall gap formation included mean time-zero and cyclic gap formation and considered the tension differences after femoral fixation between fixed and adjustable groups to allow for an objective comparison based on the achieved time-zero tension. Furthermore, the ultimate failure load and stiffness were determined, with the mechanism of failure noted. Stiffness was calculated within the linear slope of the force-displacement progression.

Statistical Analysis

In this study, the repair techniques were independent variables. All metrics for comparisons were dependent variables. Time-zero and overall gap formation as well as residual and ultimate failure loads were defined as primary outcome variables. Statistical analysis was performed using SigmaPlot software for Windows (version 13.0; Systat Software). Data analysis was performed with MATLAB (version R2018a; MathWorks). Bi-polynomial and linear regression fitting was conducted to demonstrate the correlation between outcome parameters over the whole test and groups.

Statistical analysis included a 1-way analysis of variance (ANOVA) with the Tukey post hoc test performed for significant pairwise analysis of primary outcome variables. Significance was defined as $P \leq .05$, and the desired power level was set at 0.8. The Shapiro-Wilk test was used to confirm that each data set followed a normal distribution. A nonparametric test, the Kruskal-Wallis test, was used for data sets that failed this test. For Kruskal-Wallis tests that found significance, the Tukey post hoc test was conducted to further analyze the differences. The observed post hoc average power values of all 1-way ANOVAs were much higher than the desired power level of 0.8, leading us to conclude that our sample size was sufficient.

A 1-way analysis of covariance (ANCOVA) for regression analysis of the overall gap formation as a function of residual loading was performed by comparing all groups over the whole cycling range with each other. The Shapiro-Wilk test was used to confirm that each data set followed a normal distribution. For ANCOVAs that were considered significant, the Holm-Sidak post hoc test was performed for pairwise analysis. Significance was defined as $P \leq .05$, and the desired power level was set at 0.8.

RESULTS

A significantly lower mean load of the CLS (2.31 ± 0.93 N) and anchor (5.51 ± 2.12 N) groups compared with the CLD group (12.59 ± 2.44 N; $P < .001$ for both) was found after femoral suture knot tying and anchoring (Figure 4). We also noted significantly increased time-zero gap formation to reach the defined time-zero initial load state (10 N) for the CLS (0.66 ± 0.23 mm) and anchor (0.20 ± 0.12 mm) groups compared with the CLD group (-0.05 ± 0.04 mm; $P < .001$ for both). Moreover, the CLS and anchor groups showed statistical significance for loads after fixation and time-zero gap formation.

For all techniques, the overall gap formation values, including time-zero and cyclic data at the end of each test block with resulting bi-polynomial regression curves, are shown in Figure 5. For all gap formation data, a significant difference ($P < .05$) with a mean test power of $P \geq .99$ was found between the CLS and anchor groups compared with the CLD and CLS-ALD groups. The CLS and anchor groups revealed statistical significance within cycling ranges up to 5 mm.

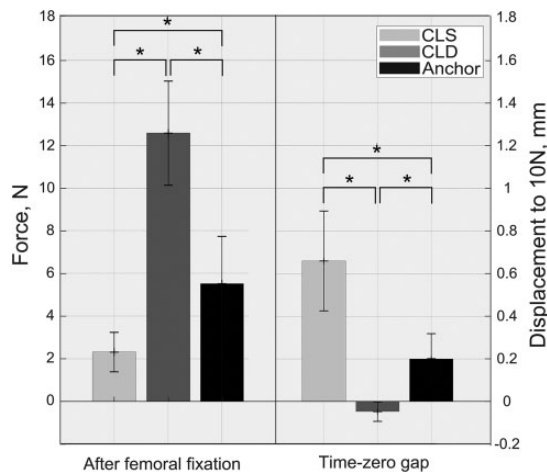


Figure 4. Mean load levels after suture knot tying and suture anchoring with time-zero gap formation to achieve the initial load level (10 N) for each anterior cruciate ligament repair technique ($n = 25$ for each group). Error bars indicate standard deviations. *Statistically significant difference: $P < .001$ (test power, $P \geq .99$).

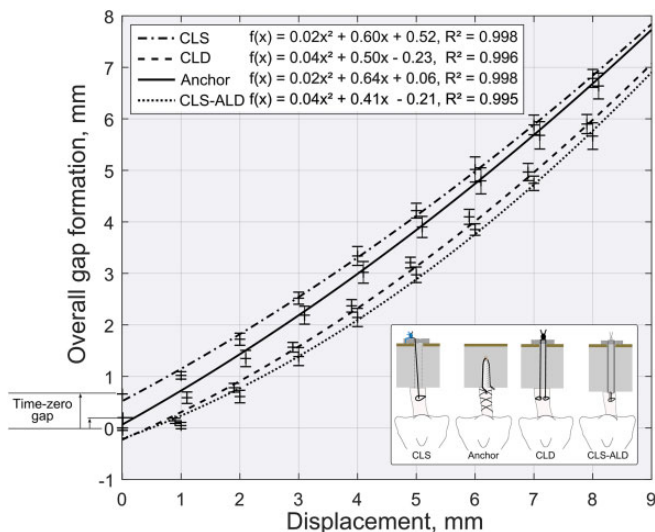


Figure 5. Mean overall gap formation over displacement at time-zero and position-controlled blocks with individual regression curves for anterior cruciate ligament repair groups. Error bars indicate standard deviations.

The mean and standard deviation of the overall gap formation and residual load data are shown within gap formation zones for each group, which were statistically compared with each other (Figure 6). Linear regression curves of the mean overall gap formation in dependence on residual peak loads provided an accuracy in the order of at least $R^2 = 0.98$ for all groups. Higher time-zero gap formation combined with reduced residual load-bearing capacity and increased gap formation gradient over the cycling range led to an overall decreased fixation strength

for the CLS, anchor, and CLD groups compared with the CLS-ALD group. The ANCOVA between all groups showed a significance level of $P < .001$.

None of the specimens failed during cyclic testing. Therefore, all constructs were subjected to a final load-to-failure test. The CLS-ALD group revealed the highest ultimate failure and stiffness, at 305.7 N and 117.1 N/mm, respectively (Figure 7). A significant difference in the ultimate failure load was found for all groups compared with the CLS group ($P < .001$). The most common mode of failure for CLS and CLD-ALD groups was knot slippage and breakage of the CL suture, respectively. The CLD and anchor groups showed 80% and 40% femoral suture tearing, respectively. Others failed because of suture slippage at the anchor and ACL fixation sites.

DISCUSSION

The most important finding of this study was that knot tying of a single CL (CLS) and knotless suture anchor fixation imparted a time-zero gap to achieve slight pretension (10 N) on the ACL repair construct, leading to significantly higher overall gap formation at reduced residual loads. Furthermore, adjustable single-CL ACL repair with preconditioning according to intraoperative workflow optimized time-zero tension and led to statistically significantly improved mechanical stabilization at reduced gap formation with the highest ultimate strength.

Open primary ACL repair historically has had poor midterm clinical outcomes, with a high incidence of reinjuries, pain, osteoarthritis, and knee instability.^{9,37,41} Recent developments in surgical techniques and understanding have led to revisiting the primary repair concept.^{1,7,8,10,17-20,28,38} To date, no studies have compared the biomechanical behavior of the different ACL repair techniques that have been reported for fixation with an ALD. Biomechanical bench test results of some of the clinically reported ACL repair techniques in this study did show significant differences in terms of stabilization and gap formation behavior, although the clinical relevance is not immediately obvious.

The amount of time-zero preload on the repaired ligament seemed to be the most influential factor in terms of gap formation and fixation strength. Knotless single-suture anchor fixation and knot tying over a cortical button resulted in reduced time-zero pretension on the ACL repair construct. The resulting increased time-zero gap in the CLS group might be mainly attributed to an unfavorable repair suture knot-tying situation, with a separate shuttle suture resulting in an eccentric knot position. After applying slight tension (10 N), the suture knot tended to migrate to a more centric button position to find its final seating. In contrast, centric knot tying in the CLD group allowed for achieving slightly increased tension on the ACL repair construct and simultaneously avoided the creation of a time-zero gap. Nevertheless, even in this more favorable knotting situation, the achieved tension was around the time-zero ACL preload (10 N) and may represent an upper tension limit for these fixed techniques. Clinical bone anchor placement

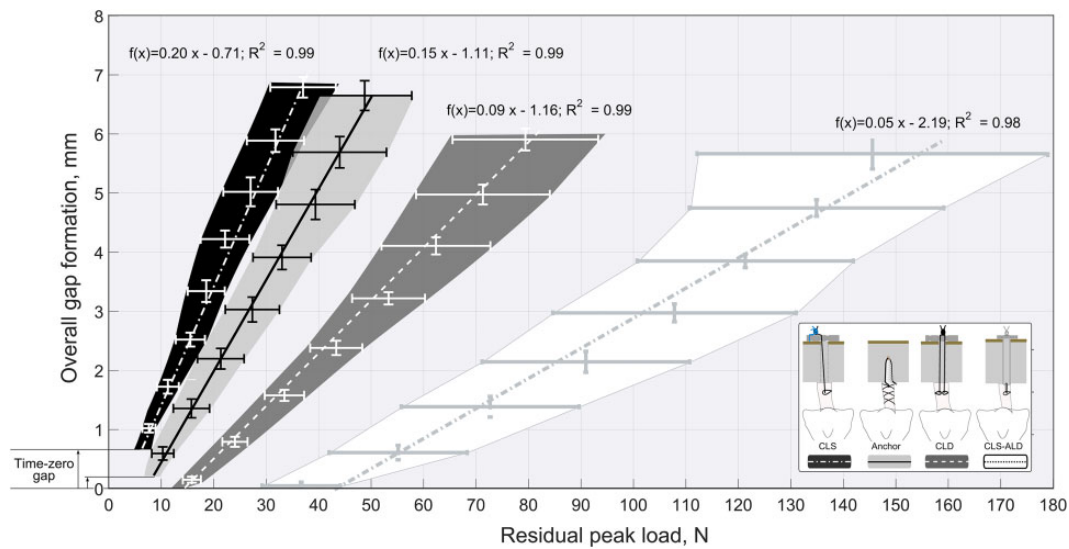


Figure 6. Mean overall gap formation over residual peak load progression with linear regression curves (time-zero gap excluded) and indicated gap formation zones (shaded, enclosing standard deviation values) for all groups.

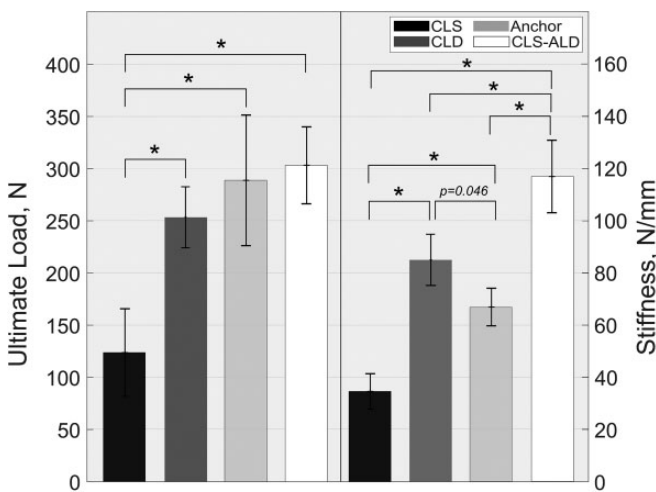


Figure 7. Mean stiffness and ultimate load values during pull to failure for all anterior cruciate ligament repair groups. Error bars indicate standard deviations. *Statistically significant difference: $P < .001$ (test power, $P \geq .99$).

requires a knee flexion position of at least 30° to provide for good visualization.¹¹ All specimens in this study were fixed at a simulated fully extended knee position to keep testing consistent. Active knee flexion from 30° or 90° to full extension causes ACL elongation of around 1 and 3 mm, respectively.²⁴ Therefore, primary fixation at increased flexion angles would presumably create even higher stress on the ACL repair construct, with resulting larger gaps at full extension or during dynamic loading.

It is unclear from the literature whether a gap between the repaired ACL tissue and the femoral wall matters or whether there is a critical size of the gap that would preclude healing. If there is a potential of ligament healing for larger gaps, residual laxity in the ACL might indicate clinical

failure (>3-mm side-to-side difference in knee laxity). However, because a time-zero gap with resultant AP laxity will not self-correct over time, the ability to precycle and retention an ACL repair construct, such as with the CLS-ALD group, is potentially crucial for optimizing mechanical stabilization, and this could be a reasonable factor that contributes to clinical success. Simulated intraoperative knee precycling over the range of motion causes initial settling effects. Subsequent retensioning eliminates the introduced primary slack and simultaneously optimizes the repair construct for later dynamic loading. Along this line of reasoning, it was encouraging that the CLS-ALD technique revealed improved performance, with a significantly higher residual load with reduced gap formation compared with all other repair techniques. It is also notable that the weak performance of simple single-CL ACL fixation became the strongest by adding an ALD and achieved even better stabilization results compared with double-CL or multiple-stitching techniques. The consistent failure mode in the CLS group was suture slipping at the knot, which again outlined that the weak link of this construct was eccentric knotting.

The treatment of a torn ACL mainly aims to restore normal AP knee laxity as well as to stabilize the knee during the time of rehabilitation. Adjustable repair specimens were primarily tensioned to a load level of 60 N, which represents minimum time-zero load-carrying capacity to protect the ACL during the first postoperative weeks with active knee movement.^{27,49,50} The recalculation of ACL force in the human knee during rehabilitation exercises using in vivo external force and limb kinematic measurements revealed peak loads up to 0.5 times body weight.⁴² These loads are more consistent with ACL loads occurring during normal daily activity for an intact knee and might be more in line with the current approach of ACL repair to allow early range of motion and accelerated rehabilitation.³³⁻³⁵ AP translation in the range of 3 to 5 mm has been

reported as normal knee laxity during knee motion as well as during an anterior drawer test.⁴⁰ Higher AP laxity after an injury may further compromise the self-healing response as well as the overall integrity of the healing environment.^{4,13} The nonoperative treatment of acute ACL ruptures with mild instability (Lachman grade ≤ 1) can allow for the restoration of joint stability, even if these injuries seem to be complete tears on magnetic resonance imaging.⁴ Independent of the repair technique, the current test results demonstrated increased gap formation with low load-bearing capability compared with normal in vivo knee kinematic requirements, indicating a low stabilization potential. The CLS and single-suture anchor techniques were not even able to meet the minimum requirement (60 N) for the restoration of knee stability within the first post-operative weeks for optimized healing conditions and may clinically fail because of the resulting considerable gap formation.

A comparison between current and previous study results is challenging because of differences in the test protocol and setup. Primary ACL repair with either cortical button or suture anchor fixation of complete proximal tears and cycling through range of flexion with simulated quadriceps force revealed a gap formation of less than 1 mm, with no significant difference between techniques.⁴⁴ Quadriceps-activated knee flexion induces contractile force and may not realistically reproduce the in vivo loading environment with the ACL under tension. Identified gaps were measured with a caliper and may underestimate the functional outcome in patients with ACL deficiency. The gap formation assessment method of using the unloaded (plastic) displacement range during cycling with the standardized time-zero position and ACL repair tension for all constructs may create more reproducible and consistent data compared with unclear manual measurements of the distance between the femoral wall and ACL remnant. Previous ultimate failure data⁴⁴ were in line with our values. Other studies using human and porcine knees found increased AP laxity of about 11 and 12 mm after primary suture stabilization of a complete ACL tear and applying shear cycling according to an anterior drawer test with no restoration of normal AP laxity.^{13,23} An anterior drawer test of the knee allows for drawing conclusions about AP laxity during a specific clinical examination but does not replicate an active loading situation during daily activity. Therefore, loading the knee in a more representative daily activity fashion combined with clinically translational anterior drawer laxity testing may provide for a better understanding of the ACL repair stabilization potential.

Limitations

We acknowledge limitations to the current study. Porcine tissue was utilized as a substitute material for human tissue. Porcine tissue has been previously reported to approximate human tissue and enabled better comparability within the testing groups because of more consistent structural properties.^{2,22,30} Additionally, loads were applied along the ACL longitudinal axis, which represents the worst-case scenario for ACL repair tests but might be

slightly different to common in vivo loading situations. This was an in vitro, time-zero biomechanical study, evaluating the stabilization potential of different ACL repair techniques without additional augmentation in the range of normal AP knee laxity. Thus, further biomechanical studies with other available techniques and including some kind of internal bracing technique should be performed to demonstrate improved stability restoration according to the in vivo functional requirements of the knee. Moreover, additional human construct tests with available surrounding soft tissue as well as short- and long-term clinical follow-up studies are needed to confirm how the findings of this study correlate with clinical outcomes.

CONCLUSION

Adjustable single-CL ACL fixation with intraoperative pre-conditioning optimized time-zero tension and led to significantly improved stabilization and reduced gap formation, with the highest ultimate strength compared with the other tested techniques. Single-CL knot tying over the button and knotless anchor fixation resulted in time-zero gaps to achieve slight tension on the ACL and significantly higher gap formation, with reduced load-bearing capability.

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REFERENCES

1. Achtnich A, Herbst E, Forkel P, et al. Acute proximal anterior cruciate ligament tears: outcomes after arthroscopic suture anchor repair versus anatomic single-bundle reconstruction. *Arthroscopy*. 2016; 32(12):2562-2569.
2. Aerssens J, Boonen S, Lowet G, Dequeker J. Interspecies differences in bone composition, density, and quality: potential implications for in vivo bone research. *Endocrinology*. 1998;139(2):663-670.
3. Aga C, Rasmussen MT, Smith SD, et al. Biomechanical comparison of interference screws and combination screw and sheath devices for soft tissue anterior cruciate ligament reconstruction on the tibial side. *Am J Sports Med*. 2013;41(4):841-848.
4. Ahn JH, Chang MJ, Lee YS, Koh KH, Park YS, Eun SS. Non-operative treatment of ACL rupture with mild instability. *Arch Orthop Trauma Surg*. 2010;130(8):1001-1006.
5. Ateschrang A, Schreiner AJ, Ahmad SS, et al. Improved results of ACL primary repair in one-part tears with intact synovial coverage. *Knee Surg Sports Traumatol Arthrosc*. 2019;27(1):37-43.
6. Beck M. *Differenzierung der funktionellen Instabilität des Kniegelenks nach Ruptur des vorderen Kreuzbandes anhand des Kreuzband-Hamstring-Reflexes*. Ulm, Germany: Medizinische Fakultät, Universität Ulm; 2011.
7. Bigoni M, Gaddi D, Gorla M, et al. Arthroscopic anterior cruciate ligament repair for proximal anterior cruciate ligament tears in skeletally immature patients: surgical technique and preliminary results. *Knee*. 2017;24(1):40-48.
8. Bucci G, Begg M, Pillifant K, Singleton SB. Primary ACL repair vs reconstruction: investigating the current conventional wisdom. *Orthop J Sports Med*. 2018;6(6 Suppl 3):2325967118S00049.
9. Cabaud E, Feagin J, Rodkey WG. Acute anterior cruciate ligament injury and augmented repair. *Am J Sports Med*. 1980;8(6):395-401.

10. Caborn DN, Nyland J, Wheeldon B, Kalloub A. ACL femoral avulsion reapproximation with internal bracing and PRP augmentation: excellent return to sports outcomes and low re-injury rates at 3 year follow-up. Presented at: Annual Meeting of the European Society of Sports Traumatology, Knee Surgery and Arthroscopy; 2018; Glasgow, UK. *ESSKA Academy*. 2018;209475:P06-248.
11. DiFelice GS, Villegas C, Taylor SA. Anterior cruciate ligament preservation: early results of a novel arthroscopic technique for suture anchor primary anterior cruciate ligament repair. *Arthroscopy*. 2015;31(11):2162-2171.
12. Feagin JA Jr, Curl WW. Isolated tear of the anterior cruciate ligament: 5-year follow-up study. *Am J Sports Med*. 1976;4(3):95-100.
13. Fleming BC, Carey JL, Spindler KP, Murray MM. Can suture repair of ACL transection restore normal anteroposterior laxity of the knee? An ex vivo study. *J Orthop Res*. 2008;26(11):1500-1505.
14. Foster TE, Wolfe BL, Ryan S, Silvestri L, Kaye EK. Does the graft source really matter in the outcome of patients undergoing anterior cruciate ligament reconstruction? An evaluation of autograft versus allograft reconstruction results: a systematic review. *Am J Sports Med*. 2010;38(1):189-199.
15. Gadikota HR, Sim JA, Hosseini A, Gill TJ, Li G. The relationship between femoral tunnels created by the transtibial, anteromedial porportal, and outside-in techniques and the anterior cruciate ligament footprint. *Am J Sports Med*. 2012;40(4):882-888.
16. Henle P, Roder C, Perler G, Heitkemper S, Egli S. Dynamic intraligamentary stabilization (DIS) for treatment of acute anterior cruciate ligament ruptures: case series experience of the first three years. *BMC Musculoskelet Disord*. 2015;16:27.
17. Hennings J. Primary anatomical repair of proximal ACL ruptures with suture anchors: 1 year follow-up. *Orthop J Sports Med*. 2018;6(4 Suppl 2):2325967118S00023.
18. Heusdens CHW, Hopper GP, Dossche L, Roelant E, Mackay GM. Anterior cruciate ligament repair with independent suture tape reinforcement: a case series with 2-year follow-up. *Knee Surg Sports Traumatol Arthrosc*. 2018;27(1):60-67.
19. Hoffmann C, Friederichs J, von Ruden C, Schaller C, Buhren V, Moessner C. Primary single suture anchor re-fixation of anterior cruciate ligament proximal avulsion tears leads to good functional mid-term results: a preliminary study in 12 patients. *J Orthop Surg Res*. 2017;12(1):171.
20. Jonkergouw A, van der List JP, DiFelice GS. Arthroscopic primary repair of proximal anterior cruciate ligament tears: outcomes of the first 56 consecutive patients and the role of additional internal bracing. *Knee Surg Sports Traumatol Arthrosc*. 2019;27(1):21-28.
21. Kaplan N, Wickiewicz TL, Warren RF. Primary surgical treatment of anterior cruciate ligament ruptures: a long-term follow-up study. *Am J Sports Med*. 1990;18(4):354-358.
22. Kato Y, Ingham SJ, Linde-Rosen M, Smolinski P, Horaguchi T, Fu FH. Biomechanics of the porcine triple bundle anterior cruciate ligament. *Knee Surg Sports Traumatol Arthrosc*. 2010;18(1):20-25.
23. Kohl S, Evangelopoulos DS, Ahmad SS, et al. A novel technique, dynamic intraligamentary stabilization creates optimal conditions for primary ACL healing: a preliminary biomechanical study. *Knee*. 2014;21(2):477-480.
24. Li G, DeFrate LE, Rubash HE, Gill TJ. In vivo kinematics of the ACL during weight-bearing knee flexion. *J Orthop Res*. 2005;23(2):340-344.
25. Marshall JL, Warren RF, Wickiewicz TL. Primary surgical treatment of anterior cruciate ligament lesions. *Am J Sports Med*. 1982;10(2):103-107.
26. Monaco E, Fabbri M, Lanzetti RM, Del Duca A, Labianca L, Ferretti A. Biomechanical comparison of four coupled fixation systems for ACL reconstruction with bone socket or full-tunnel on the tibial side. *Knee*. 2017;24(4):705-710.
27. More RC, Markolf KL. Measurement of stability of the knee and ligament force after implantation of a synthetic anterior cruciate ligament: in vitro measurement. *J Bone Joint Surg Am*. 1988;70(7):1020-1031.
28. Mukhopadhyay R, Shah N, Vakta R, Bhatt J. ACL femoral avulsion repair using suture pull-out technique: a case series of thirteen patients. *Chin J Traumatol*. 2018;21(6):352-355.
29. Noonan BC, Bachmaier S, Wijdicks CA, Bedi A. Intraoperative preconditioning of fixed and adjustable loop suspensory anterior cruciate ligament reconstruction with tibial screw fixation: an in vitro biomechanical evaluation using a porcine model. *Arthroscopy*. 2018;34(9):2668-2674.
30. Proffen BL, McElfresh M, Fleming BC, Murray MM. A comparative anatomical study of the human knee and six animal species. *Knee*. 2012;19(4):493-499.
31. Relph N, Herrington L, Tyson S. The effects of ACL injury on knee proprioception: a meta-analysis. *Physiotherapy*. 2014;100(3):187-195.
32. Seitz H, Wielke B, Schlenz I, Pichl W, Vecsei V. Load sharing in augmented anterior cruciate ligament repair: a mathematical analysis based on in vitro measurements. *Clin Biomech (Bristol, Avon)*. 1996;11(8):431-438.
33. Shelburne KB, Pandey MG. Determinants of cruciate-ligament loading during rehabilitation exercise. *Clin Biomech (Bristol, Avon)*. 1998;13(6):403-413.
34. Shelburne KB, Pandey MG. A dynamic model of the knee and lower limb for simulating rising movements. *Comput Methods Biomech Biomed Engin*. 2002;5(2):149-159.
35. Shelburne KB, Pandey MG, Anderson FC, Torry MR. Pattern of anterior cruciate ligament force in normal walking. *J Biomech*. 2004;37(6):797-805.
36. Sherman MF, Bonamo JR. Primary repair of the anterior cruciate ligament. *Clin Sports Med*. 1988;7(4):739-750.
37. Sherman MF, Lieber L, Bonamo JR, Podesta L, Reiter I. The long-term followup of primary anterior cruciate ligament repair: defining a rationale for augmentation. *Am J Sports Med*. 1991;19(3):243-255.
38. Smith JO, Yaseen SK, Palmer HC, Lord BR, Britton EM, Wilson AJ. Paediatric ACL repair reinforced with temporary internal bracing. *Knee Surg Sports Traumatol Arthrosc*. 2016;24(6):1845-1851.
39. Sung Kim H, Keun Seon J, Reum Jo A. Current trends in anterior cruciate ligament reconstruction. *Knee Surg Relat Res*. 2013;25(4):165-173.
40. Taylor KA, Cutcliffe HC, Queen RM, et al. In vivo measurement of ACL length and relative strain during walking. *J Biomech*. 2013;46(3):478-483.
41. Taylor SA, Khair MM, Roberts TR, DiFelice GS. Primary repair of the anterior cruciate ligament: a systematic review. *Arthroscopy*. 2015;31(11):2233-2247.
42. Toutoungi DE, Lu TW, Leardini A, Catani F, O'Connor JJ. Cruciate ligament forces in the human knee during rehabilitation exercises. *Clin Biomech (Bristol, Avon)*. 2000;15(3):176-187.
43. Toy BJ, Yeasting RA, Morse DE, McCann P. Arterial supply to the human anterior cruciate ligament. *J Athl Train*. 1995;30(2):149-152.
44. van der List JP, DiFelice GS. Gap formation following primary repair of the anterior cruciate ligament: a biomechanical evaluation. *Knee*. 2017;24(2):243-249.
45. van der List JP, DiFelice GS. Primary repair of the anterior cruciate ligament: a paradigm shift. *Surgeon*. 2017;15(3):161-168.
46. van der List JP, DiFelice GS. Role of tear location on outcomes of open primary repair of the anterior cruciate ligament: a systematic review of historical studies. *Knee*. 2017;24(5):898-908.
47. van Eck CF, Limpisvasti O, ElAttrache NS. Is there a role for internal bracing and repair of the anterior cruciate ligament? A systematic literature review. *Am J Sports Med*. 2017;46(9):2291-2298.
48. Warren RF. Primary repair of the anterior cruciate ligament. *Clin Orthop Relat Res*. 1983;172:65-70.
49. Wascher DC, Markolf KL, Shapiro MS, Finerman GA. Direct in vitro measurement of forces in the cruciate ligaments, part I: the effect of multiplane loading in the intact knee. *J Bone Joint Surg Am*. 1993;75(3):377-386.
50. Woo SL, Livesay GA, Engle C. Biomechanics of the human anterior cruciate ligament: muscle stabilization and ACL reconstruction. *Orthop Rev*. 1992;21(8):935-941.